



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,578	09/10/2003	Zsuzsanna Nagy	43962-010810	4669

48329 7590 09/19/2006

FOLEY & LARDNER LLP  
111 HUNTINGTON AVENUE  
26TH FLOOR  
BOSTON, MA 02199-7610

EXAMINER

BURKHART, MICHAEL D

ART UNIT PAPER NUMBER

1633

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/659,578

Applicant(s)

NAGY, ZSUZSANNA

Examiner

Michael D. Burkhardt

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 19-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Upon consideration of the correction of improper multiple dependencies of claims 7-10 and 13-18 by the amendment dated 6/28/2006, the pending claims within original Group I (restriction requirement dated 4/22/2005) are subject to further restriction as follows. The original restriction of Groups II and III is maintained for reasons made of record in the previous restriction requirement, and the respective claims are now in Groups VIII and IX, as set forth below.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 7, drawn to methods of diagnosing Alzheimer's' disease by testing the responsiveness of cells to a substance in a cell proliferation assay, classified in class 435, subclass 366.
- II. Claim 8, drawn to methods of diagnosing Alzheimer's' disease by testing the responsiveness of cells to a substance by a relative lengthening of the G1 phase, classified in class 435, subclass 375.
- III. Claims 9 and 10, drawn to methods of diagnosing Alzheimer's' disease by testing the responsiveness of cells to a substance by analysis of expression of a cell cycle regulatory protein, classified in class 435, subclass 366.
- IV. Claims 11 and 12, drawn to methods of diagnosing Alzheimer's' disease by testing the responsiveness of cells to a substance by analysis of a DNA damage-response element, classified in class 435, subclass 366.

Art Unit: 1633

- V. Claim 13, drawn to methods of diagnosing Alzheimer's' disease by testing the responsiveness of cells to a substance by assessment of cell viability, classified in class 435, subclass 375.
- VI. Claims 14 and 15, drawn to methods of diagnosing Alzheimer's' disease by testing the responsiveness of cells to a substance by analysis of a expression of a cell death related protein, classified in class 435, subclass 366.
- VII. Claim 16, drawn to methods of diagnosing Alzheimer's' disease by testing the responsiveness of cells to a substance by assessment of DNA content of the cells, classified in class 435, subclass 6.
- VIII. Claims 19-27, drawn to methods of diagnosing Alzheimer's' disease through genetic screening, classified in class 435, subclass 6.
- IX. Claims 28-29, drawn to methods for identifying compounds with potential pharmacological activity against Alzheimer's' disease, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-VII are biologically and functionally distinct from each other and thus one does not render the other obvious. The methods of Groups I-VII comprise method steps which are distinct from each other: the step of measuring cell proliferation in Group I is not found in the other Groups; the step of measuring G1 phase lengthening in Group II is not found in the other Groups; the step of measuring expression of a cell cycle regulatory protein in Group III is not found in the other Groups; the step of analysis of DNA damage-response in Group IV is not found in the other Groups; the step of measuring cell viability in Group V is not found within

Art Unit: 1633

the other Groups; the step of measuring expression of a cell death related protein in Group VI is not found within the other Groups; and the step of assessment of DNA content of cells is not found within the other Groups. The end result of the methods are different, each has a different output and requires distinct reagents and method steps. Thus, the operation, function and effects of these different methods are distinct from each other and therefore are capable of supporting separate patents. Furthermore, the search for the above Groups is considered to overlap to some degree, but is not coextensive, and thus is considered burdensome. For example, searching for methods of Alzheimer's diagnosis by measurement of cell proliferation would not discover such methods measuring protein expression, and vice versa.

Claims 1-3 and 5 link(s) inventions I to VII. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1-3 and 5. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections

Art Unit: 1633

over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

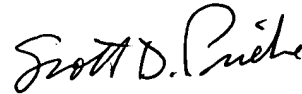
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1633

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart  
Examiner  
Art Unit 1633

A handwritten signature in black ink, reading "Scott D. Pribe". The signature is written in a cursive, flowing style.

SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER